Attorney's Docket No.: 5513P021

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Hassan Mostafavi

Application No. 10/664,213

Filed: September 16, 2003

For: LOCALIZATION OF A TARGET USING

IN VIVO MARKERS

Examiner: Jonathan Cwern

Group Art Unit: 3737

Confirmation No. 3361

APPEAL BRIEF

Mail Stop Appeal Brief – Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Applicants ("Appellants") submit the following Appeal Brief pursuant to 37 C.F.R. §41.37(c) for consideration by the Board of Patent Appeals and Interferences. A payment in the amount of \$540.00 was submitted with the Notice of Appeal filed on October 13, 2010, as required by 37 C.F.R. §41.20(b)(1). A payment in the amount of \$540.00 is submitted herewith as required by 37 C.F.R. §41.20(b)(2).

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I. REAL PARTY IN INTEREST

Hassan Mostafavi, Larry D. Partain, Alexander Sloutsky and Peter Munro, named as the inventors on the application, transferred their rights in the subject application through an assignment executed on October 30, 2003, November 6, 2003, November 6, 2003, and November 11, 2003 to Varian Medical Systems Technologies, Inc., having a principal place of business in Palo Alto, California, recorded at reel/frame number 014712/0730. These rights were then transferred by Varian Medical Systems Technologies, Inc. through an assignment executed on September 26, 2008 to Varian Medical Systems, Inc., having a principal place of business in Palo Alto, California, recorded at reel/frame number 021631/0973. Accordingly, Varian Medical Systems, Inc. is the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in this Appeal.

III. STATUS OF CLAIMS

Claims 1, 3, 5-16, 49, 51-58, 62-79, and 81-89 are pending in the application. Claims 1, 3, 5-16, 49, 51-58, 62-79, and 81-89 were examined and rejected in the current Final Office Action mailed July 13, 2010 ("the Office Action"). Claims 2, 4, 17-48, 50, 59-61 and 80 were previously cancelled.

Independent claims 1, 49 and 54; and dependent claims 62-64, 82 and 88 are Appealed herein.

IV. STATUS OF AMENDMENTS

No amendments were submitted after the Final Office Action was mailed.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 recites a method comprising:

imaging a plurality of markers in a first imaging modality, wherein at least a plurality of the markers are implanted completely internally in a body (see at least Figures 1A-B, 4, and 6; and paragraphs 7, 35, 37, 47-48, and 50-57);

determining first coordinates of the plurality of markers relative to a first beam isocenter and internal to the body (see at least Figures 1A-B, 4, and 6; and paragraphs 7, 48, and 50-57);

imaging the plurality of markers in a different second imaging modality (see at least Figures 1A-B, 4, and 6; and paragraphs 7, 35, 37, 48, and 50-57); and

determining second coordinates of the plurality of markers relative to a second beam isocenter and internal to the body (see at least Figures 1A-B, 4, and 6; and paragraphs 7, 48, and 50-57), wherein at least a plurality of said markers are implanted in soft tissue of the body (see at least Figures 1A-B, 4, and 6; and paragraphs 4, 6, 37, 45 and 47-48), wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging (see at least Figures 1A-B, 4, and 6-15; and paragraphs 35, 42-44 and 48-57).

Independent claim 49 recites an apparatus, comprising:

means for imaging a plurality of markers in a first imaging modality, wherein at least a plurality of the markers are implanted completely internally in a body (see at least Figures 1A-B, and 4-6; and paragraphs 7, 35, 37, 47-48, and 50-57);

means for determining first coordinates of the plurality of markers internal to the body and relative to a first beam isocenter of a first beam source of the first imaging modality (see at least Figures 1A-B, and 4-6; and paragraphs 7, 48, and 50-57);

means for imaging the plurality of markers in a different second imaging modality (see at least Figures 1A-B, and 4-6; and paragraphs 7, 35, 37, 48, and 50-57); and

means for determining second coordinates of the plurality of markers internal to the body and relative to a second beam isocenter of a second beam source of the second imaging modality (see at least Figures 1A-B, and 4-6; and paragraphs 7, 48, and 50-57), wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging (see at least Figures 1A-B, and 4-15; and paragraphs 35, 42-44 and 48-57).

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Independent claim 54 recites a system, comprising:

a first beam source to generate an imaging beam having a first beam isocenter (see at least Figures 1A-B, 4, and 6; and paragraphs 7, 35, 37, 47-48, and 50-57);

a second beam source to generate a treatment beam having a second beam isocenter (see at least Figures 1A-B, 4, and 6; and paragraphs 7, 35, 37, 48, and 50-57);

a first imager coupled to receive the imaging beam, the first imager to image a plurality of markers, wherein at least a plurality of the markers are implanted completely internally in a body, in a first imaging modality (see at least Figures 1A-B, 4, and 6; and paragraphs 7, 35, 37, 48, and 50-57);

a second imager coupled to receive the treatment beam, the second imager to image the plurality of markers in a different second imaging modality (see at least Figures 1A-B, 4, and 6; and paragraphs 7, 35, 37, 48, and 50-57); and

a computer coupled to the first and second imagers (see at least Figures 4 (e.g., feature 510), 5 and 15; and paragraphs 16, 34, and 62-71), the computer to determine first coordinates of the plurality of markers relative to the first beam isocenter and internal to the body and determine second coordinates of the plurality of markers relative to the second beam isocenter and internal to the body (see at least Figures 1A-B, and 4-6; and paragraphs 7, 48, and 50-57), wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging (see at least Figures 1A-B, and 4-15; and paragraphs 35, 42-44 and 48-57).

Dependent claim 62 recites the method of claim 1, and further requires: adjusting a position of a target volume within the body relative to a treatment beam using the plurality of internal markers imaged using the first imaging modality having an external source and the second imaging modality having an external source (see at least Figures 1A-B, 4 and 6; and paragraphs 36, 83 and 93).

Dependent claim 63 recites the method of claim 1, and further requires: estimating an adjustment to at least one of the body and a treatment beam in a treatment session, based on a

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determination of any change of spacing between imaged markers implanted in a target, over a course of multiple treatment sessions, and based on a number of visible markers in the imaged markers (see at least Figures 1A-B, and 4-15; and paragraphs 35, 56, 64, 73, 77-76,83, 93, 96 and 98).

Dependent claim 64 recites the method of claims 1 and 63, and further requires: estimating a number of positioning images needed for the treatment session based on a determination of any change of spacing between imaged markers implanted in a target, over a course of treatment, and based on the number of visible markers in the image (see at least Figures 1A-B, and 4-15; and paragraphs 35, 56, 64, 73, 77-76,83, 93, 96 and 98).

Dependent claim 82 recites the method of claim 1, and further requires: wherein the first beam isocenter is determined at a treatment planning machine during a treatment planning stage, the second beam isocenter is a treatment machine beam isocenter during a treatment, and the treatment planning machine and the treatment machine are different machines (see at least Figures 1A-B, and 4-15; and paragraphs 35, 56, 64, 73, 77-76,83, 93, 96 and 98).

Dependent claim 88 recites the method of claim 1, and further requires wherein the first beam isocenter is a planned isocenter determined at a planning machine at a time of planning using an image from the first imaging modality, wherein the second beam isocenter is a treatment machine beam isocenter of a treatment machine at a time of treatment, and wherein the second imaging modality is arranged to provide an image of the patient at the treatment machine (see at least Figures 1A-B, and 4-15; and paragraphs 35, 56, 64, 73, 77-76,83, 93, 96 and 98).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether independent claims 1, 49 and 54; and dependent claims 62, 82 and 88 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0193685 to Mate et al. (Mate) in view of U.S. Publication No. 2002/0065461 to Cosman (Cosman) and further in view of U.S. Patent Pub. No. 2003/0007601 to Jaffray et al. (Jaffray).

Whether dependent claims 63-64 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0193685 to Mate et al. (Mate) in view of U.S.

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Publication No. 2002/0065461 to Cosman (<u>Cosman</u>) and U.S. Patent Pub. No. 2003/0007601 to Jaffray et al. (<u>Jaffray</u>) and further in view of U.S. Patent No. 6,073,044 to Fitzpatrick et al. (Fitzpatrick).

All the claims do not stand or fall together. The basis for the separate patentability of the claims is set forth below under each separate claim heading.

VII. ARGUMENT

A. Overview of the Cited References

1.) <u>Mate</u>

Mate teaches allowing target 12 to be accurately positioned at a treatment machine isocenter by aligning target and machine isocenters 40 and 22 for radiation delivery from source 18 to irradiate a target (see paragraphs 35 and 39). Mate teaches that markers 30 can be located (but not imaged) by exciting markers 30 with excitation source 32 so that markers 30 resonate at a selected unique frequency and generate an underlying low energy radio-frequency magnetic signal measurable from outside body 14 by array 34 of sensors 36 (see paragraph [0036]). The primary purpose of Mate is to calculate the position of the target 12 as compared to the markers 30 around the target 12 so that during treatment, the markers 30 can be excited with excitation source 32 to resonate at a low energy radio-frequency magnetic signal, measurable from outside the body, in order to ensure proper positioning of the target (see Mate paragraphs 35-39 and 60-62). Excited markers 30 and reference device 42 are located relative to the reference coordinate system 72 using array 34 of sensors 36 to detect the radio-frequency signals of markers 30 and reference device 42 (see Mate paragraphs 37, 48-55). The location of markers 30 as compared to the location of target 12 is calculated using reference device 42 which is at a known position relative to machine isocenter 22 (and thus is at a known position relative the target 12), and provides a radio-frequency signals detected and located the markers 30 by array 34 sensors 36 (see Mate paragraph 38). The location of markers 30 relative to the reference coordinate system 72, can be added by computer controller 38 to imaging data (see Mate paragraph 54-55). Mate described that the imaging data "defines locations of each marker 30." (see Mate paragraph 60 and 62). However, there is no description of markers 30 being imageable or being imaged.

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As stated in paragraph 74 of <u>Mate</u>, the claims and descriptions of <u>Mate</u> are bound by the descriptions of "the specific embodiments disclosed in the specification" which all require excitable markers 30 (see paragraph 74 and Figs. 1-7). For example, paragraph 74 of <u>Mate</u> only provides "boilerplate" type language, but does not mention any specific monitoring system, apparatus, or methods. <u>Mate</u> discourages and criticizes the use of external non-excitable markers (see paragraphs 7-8). <u>Mate</u> is not helped by surface mounted markers (see paragraphs 65-68) and is not helped by additional internal markers in addition to markers 30 (see <u>Mate</u> paragraphs 60-62).

2.) Cosman

The primary purpose of Cosman is to align external markers for external treatment apparatus to specific targets within the body (see paragraphs 8 and 9). The camera of Cosman images the external markers relative to photons reflected from the external markers (see paragraphs 31 and 102). For example, Cosman teaches percutaneously fixing a stud section to the iliac crest bone of the pelvis during treatment, so that an array of external marker spheres can be attached to the stud above the surface of the skin at the time of treatment (see paragraph [0061] and Figure 3C). The markers have shapes and markings that are visible to a camera to indicate their locations and orientations (see paragraph [0063]). Cosman requires the camera to take images of the external fiducial markers 20, 21, 23 and 24 to identify locations on the patient (see paragraph 64 and Figs. 1-3). Although additional x-ray imaging is mentioned to refine internal target positioning to an isocenter (see paragraphs 31 and 67), Cosman only describes that diagnostic X-rays from machines, or high energy X-rays for portal imaging can be used to visualize markers prior to treatment (paragraph 67). Moreover, the "index markers" mentioned at the end of paragraph 67 of Cosman refer to Cosman's external markers that are either secured to the patient's skin (see paragraphs [0057]-[0060]) or attached to bone but exposed to the camera (e.g., they are internal studs that have external markers extended so that they are "visible" to camera; see paragraph [0061] and Figure 3C). The primary purpose of Cosman is to have the markers external to the skin so that they can be imaged with a camera in order to provide an optical tracking system to compare the location of the markers in images picked up a camera system to align the target with the isocenter of a beam (see paragraphs [0064]-[0066] and Figure 3C).

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3.) Jaffray

Jaffray teaches the kV or MV imaging during radiation treatment of a patient (see paragraph 8).

B. The Patent Office rejects independent claims 1, 49 and 54; and dependent claims 62, 82 and 88 under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0193685 to Mate et al. (Mate) in view of U.S. Publication No. 2002/0065461 to Cosman (Cosman) and further in view of U.S. Patent Pub. No. 2003/0007601 to Jaffray et al. (Jaffray).

1. Independent claim 1

In order to establish a *prima facie* case for obviousness it must be shown that the cited references, combined, teach or suggest each element of the claim. See M.P.E.P § 2143, *In re Rinehart*, 531 F.2d 1048 (C.C.P.A. 1976) ("A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art"). Further, the combination of elements must be "more than predictable use of prior art elements according to their established functions." (See *KSR International Co. v. Teleflex Inc.*, No. 04-1350 (Supreme Court, April 30, 2007)). The claims argued below do not stand or fall together but rather are argued separately in separate groups as indicated in this brief.

Appellants respectfully disagree with the rejection above for claim 1 for at least the reason that the cited references do not teach or enable a method comprising: imaging a plurality of markers in a first imaging modality, wherein at least a plurality of the markers are implanted completely internally in a body; determining first coordinates of the plurality of markers relative to a first beam isocenter and internal to the body; imaging the plurality of markers in a different second imaging modality; and determining second coordinates of the plurality of markers relative to a second beam isocenter and internal to the body, wherein at least a plurality of said markers are implanted in soft tissue of the body, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging, as required by claim 1.

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The References Do Not Properly Teach The Limits Of Claim 1

The Office Action argues that Cosman does not rely upon camera imaged markers but provides for initial CT scanning at paragraph [0064], and further refinement at paragraph [0067] (see final paragraph of page 9 through first paragraph of page 10 of the Office Action). However, Cosman requires camera imaged markers to identify locations on the patient (see paragraph [0064]). Further, although patient setup in Cosman can be refined by x-ray imaging to refine internal target positioning to an isocenter is described at paragraph [0067], Cosman still requires camera imaged markers (see paragraph 65) prior to treatment (see paragraph 67) to complete patient setup. Moreover, the "index markers" mentioned at the end of paragraph 67 of Cosman refer to Cosman's external markers that are either secured to the patient's skin (see paragraphs 57-60) or attached to bone but exposed to the camera (e.g., they are internal study that have external markers extended so that they are "visible" to camera; see paragraph [0061] and Figure 3C). That is, the Office Action appears to misinterpret paragraph 67 of Cosman, out of context, without considering that the entire purpose and enablement of Cosman is to use external markers that can be imaged by a camera (see at least Figs. 1-3). Thus, the Office Action fails to address Cosman as a whole, and improperly applying Cosman in rejecting claim 1. Cosman does not teach imaging a plurality of the markers that are implanted completely internally in a body as required by claim 1.

Similarly, the Office Action cites paragraph 74 of Mate (see lines 7-8 of page 5 of the current Office Action; and final paragraph of page 10 through first paragraph of page 11 of the Office Action), which does not provide any specifics but only "boilerplate" type language regarding Appellants' claims. For example, paragraph 74 of Mate does not mention any specific monitoring system, apparatus, or method; or any limit of the claims. Consequently, Appellants traverse that Mate teaches or can be combined with anything that teaches imageable markers, or markers other than ones that are located (but not imaged) by being RF excitable (see Mate paragraphs 35-62), and respectfully request the Patent Office provide a reference in support of this Official Notice teaching the limits of the claims, in accordance with MPEP 2144.03. Notably, Mate teaches that markers 30 can be located (but not imaged) by exciting markers 30 with excitation source 32 so that markers 30 generate an underlying low energy radio-frequency magnetic signal measurable from outside body 14 by array 34 of sensors 36 (see paragraph [0036]). The primary purpose of Mate is to calculate the position of the target 12 as compared to

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the markers 30 around the target 12 so that during treatment, the markers 30 can be excited with excitation source 32 to ensure proper positioning of the target (see Mate paragraphs 35-39 and 60-62). Excited markers 30 and reference device 42 are located relative to the reference coordinate system 72 using array 34 of sensors 36 to detect the radio-frequency signals of markers 30 and reference device 42 (see Mate paragraphs 37, 48-55). The location of markers 30 as compared to the location of target 12 is calculated using reference device 42 which is at a known position relative to machine isocenter 22 (and thus is at a known position relative the target 12), and provides a radio-frequency signals detected and located the markers 30 by array 34 sensors 36 (see Mate paragraph 38).

Next, Mate does not determining first and second coordinates of the plurality of markers relative to a first and second beam isocenter as required by claim 1. Instead, Mate allows target 12 to be accurately positioned at a treatment machine isocenter by aligning target and machine isocenters 40 and 22 for radiation delivery from source 18 to irradiate a target (see paragraphs 35 and 39).

Moreover, as stated in paragraph 74 of <u>Mate</u>, the claims and descriptions of <u>Mate</u> are still bound by the descriptions of "the specific embodiments disclosed in the specification" which all require excitable markers 30 (see Figs. 1-7). It is well settled that a reference can only be used to teach the subject matter as set forth therein, and must be considered as a whole. Ironically, the Office Action attempts to then eviscerate this requirement by <u>not</u> using the RF-excitable marker location system of <u>Mate</u>, <u>after adding</u> the RF marker signal location system of <u>Mate</u> to <u>Cosman</u> (see final paragraph of page 4 through the first paragraph of page 5 of the current Office Action).

The References Can Not Be Properly Combined to Teach The Limits Of Claim 1

The Office Action appears to rely upon adding the imaging mode of <u>Cosman</u> to the RF location mode of <u>Mate</u> in order to provide the first and second imaging modalities claimed; and then not using the RF location mode taught by <u>Mate</u>, which requires RF excitable (but not imaged) markers (see page 4, final paragraph through page 5, first paragraph of the current Office Action). Appellant believes this logic is unreasonable for at least the following reasons. After reading <u>Mate</u> and <u>Cosman</u> it is unreasonable that a person would consider combining the RF-excitable internal marker, location determination system of <u>Mate</u> in addition to the camera external marker imaging system of <u>Cosman</u>, but then not using the RF-excitable markers

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required by each embodiment of <u>Mate</u>, because the result is simply imaging external markers using the camera of <u>Cosman</u>. Second, it is hard to imagine why a person would redundantly locate external markers by using the external imaging system of <u>Cosman</u> and then locate RF-excitable markers using the imaging system of <u>Mate</u>, other than <u>only</u> to read on Appellants claims.

In addition, there is no point in combining, or enablement for combining the un-imaged RF marker system of <u>Mate</u> with the external camera imaged marker system of <u>Cosman</u>. It is unclear how the RF marker system of <u>Mate</u> would calculate the position of reference device 42 relative to the external camera imaged marker system of <u>Cosman</u>. Similarly, is unclear how the external camera imaged marker system of <u>Cosman</u> would calculate the position of the RF markers of <u>Mate</u>.

The citations of <u>Cosman</u> above also apply to why a practitioner would not attempt to combine the visible camera markers of <u>Cosman</u> with the kV or MV imaging of <u>Jaffray</u> (see paragraph 8), as argued in the Office Action (see second to last paragraph of page 4, third paragraph of page 11). That is, <u>Cosman</u> only describes imaging using visible light prior to treatment (paragraph 67 of Cosman only teaches that diagnostic X-rays from machines, <u>or</u> high energy X-rays for portal imaging can be used to visualize markers <u>prior to treatment</u>), while Jaffray is cited for treatment imaging using x-ray. Thus, a practitioner would <u>not</u> add MV treatment imaging of <u>Jaffray</u> to pre-treatment imaging of <u>Cosman</u> since they are different modes of imaging. One skilled in the art would not use x-ray to image external markers of Cosman since visible light camera would be sufficient. It would unnecessarily over-radiate the patient and does not provide any benefit (other than only reading on the claims; e.g., kV imaging is superior to MV imaging for pre-treatment imaging).

Next, to read on the first and second imaging modalities claimed, the Office Action cites a motivation of adding the imaging system of Cosman to the system of Mate, to "increase the accuracy of the alignment" (see lines 1-2 of page 5 of the Office Action). This adds the imaging system of Cosman to the RF marker location system of Mate to locate redundantly what is already located in Mate purportedly to accomplish this. However, the Office Action (1) does not describe how using the external camera imaging and RF marker location systems will increase the accuracy of the alignment, (2) does not provide any evidence that redundantly locating

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markers using those two systems will actually increase accuracy of alignment, and (3) does not describe how the two systems can be combined during planning and/or treatment. For example, the Office Action does not describe how it is possible to calculate the position of the external camera markers of <u>Cosman</u> as compared to the location of the RF markers required in <u>Mate</u>.

Also, for example, the Office Action has not sufficiently established that an "increase the accuracy of alignment" is recognized as a result effective variable. In establishing a result-effective variable, a particular parameter must first be recognized as a result-effective variable. See MPEP 2144.05. For example, in *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977), applicant claimed a wastewater treatment device having a particular tank volume to contractor area. (*In re Antonie*, 559 F.2d 618) The prior art failed to recognize treatment capacity as a function of the tank volume to contractor area ratio. (*Id.*) On this basis the court concluded the parameter optimized (i.e. treatment capacity) was not recognized in the art to be a result-effective variable. (*Id.*)

Next, the Office Action cites motivation of adding the imaging system of Cosman to the location system of Mate, to "increase the accuracy of the alignment" (see lines 1-2 of page 5 of the Office Action) seems to be purely made up without any consideration that the combination will increase equipment costs, operational costs, and treatment time. That is, this motivation seems to use the second location systems at a planning and/or pre-treatment procedure to confirm imaging done with the first system. On the other hand, as noted in the present application, without limitation thereto, one reason for using a first and second imaging modality in the field of x-ray treatment is to first locate markers on a treatment planning machine using the first modality, and at another time image the markers on a different treatment machine using the second imaging modality for patient/target positioning (e.g. see claim 84). This allows for a thorough amount of planning images and plan generation, followed by efficient use of treatment resources and treatment patient positioning (e.g., shorter treatment times). As is known, planning machines and/or treatment simulators may reduce the time of actual treatment, since treatment machine time is expensive. Thus, Office Action's proposal will increase costs and procedure time, which are not desirable.

In addition, Appellants respectfully disagree that (e.g., other than based entirely on Appellants claims) any practitioner would find motivation for, or enabled embodiments of, a

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combination of the implanted excitable markers located with RF sensors of Mate (see Figs. 1-7) with the external, camera imaged markers of <u>Cosman</u> (see Figs. 1-3) or imaging of <u>Jaffray</u> (see paragraph 8). Clearly, it is not possible for these two types of markers to be combined into a single marker embodiment, as the implanted excitable marker of <u>Mate</u> is unable to satisfy the external camera visible marker of <u>Cosman</u>; and the external camera visible marker of <u>Cosman</u> is unable to be the implanted excitable marker located with an RF sensor of <u>Mate</u>. In fact, <u>Mate</u> teaches against using external non-excitable markers (see <u>Mate</u> paragraphs 7-8) by discouraging or otherwise criticizing the use of external non-excitable markers (see the end of paragraph 8) (*Depuy Spine, Inc. v Medtronic Sofamor Danek, Inc.*, CFAC Docket 2008-1240, -1253, -1401, decided June 1, 2009, page 14-15, discouraging or otherwise criticizing certain embodiment of a reference is considered teaching away and is against motivation to combine) (also see MPEP 2141.02 and 2143.01)).

Moreover, there is no benefit, use, or reason for the art to be taken in combination. Mate uses implanted excitable markers that are located with RF sensors, which can not sense nonexcitable markers, such as the markers of Cosman. Conversely, Cosman teaches markers visible to a camera which can not sense optically invisible markers, such as the markers of Mate (Mate teaches against using external markers at paragraphs 7-8). The primary purpose of Mate is to image a target and locate markers 30 around the target so that during treatment, the markers can be excited with excitation source 32 to resonate at a low energy radio-frequency magnetic signal measurable from outside the body, without imaging markers 30 (see Mate paragraph 38), in order to ensure proper positioning of the target (see Mate paragraphs 35-39 and 60-62). Thus, there is no use, benefit or motivation for a practitioner to add a second RF location system modality to Mate. Moreover, a practitioner would not attempt to combine the external fiducial markers (e.g., markers 20, 21, 23 and 24) mentioned in Cosman (see Cosman paragraphs 31 and 67) with Mate because (1) Mate is not helped by additional surface mounted markers in addition to markers 30 (see Mate paragraphs 65-68) and (2) Mate is not helped by additional internal markers in addition to markers 30 (see Mate paragraphs 60-62). Thus, Appellants assert that the combination of Mate with Cosman appears as impermissible hindsight and is not enabled.

Next, the combination of <u>Mate</u> with <u>Cosman</u> would result in the anchored externally visible markers of <u>Cosman</u> combined with the RF sensors of Mate, which still doesn't disclose or suggest the claimed markers that are implanted completely internally to a body, and imaged

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using CT, and imaged using kV or MV imaging, as required by claim 1. That is, neither the implanted excitable markers of <u>Mate</u>, the camera visible markers of <u>Cosman</u>, nor the combination teach the above noted markers. Neither reference coordinates images from two different imaging modes.

The References Do Not Provide Benefits Of Embodiments Of Claim 1

Finally, by imaging markers wherein at least a plurality of the markers are residing completely internally in a body in two modalities, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kV and MV imaging, some embodiments described in the specification, for example, without limitation thereto, may provide one or more of: (1) the benefit of imaging in an x-ray imaging modality is an isocenter of an x-ray image system, and imaging in a second x-ray imaging modality using a high energy beam of radiation of a treatment machine (see paragraphs [0043], [0048] and [0055]-[0057] and [0074] of the Application; and claims 49 and 54); and (2) setting up a treatment plan using CT images of anatomy, tumor, and the markers; and then using kV and/or MV imaging to quickly, properly position a patient during treatment to ensure accurate placement of the tumor based on the imaged markers, for irradiating the tumor with the treatment beam (see at least paragraphs 53-54 of the Application; and claims 62-75, 82-84 and 88-89). However, the references do not contemplate or enable such benefits.

2. Independent claim 49

Appellants respectfully disagree with the rejection above for claim 49 for at least the reason that the cited references do not teach or enable an apparatus, comprising: means for imaging a plurality of markers in a first imaging modality, wherein at least a plurality of the markers are implanted completely internally in a body; means for determining first coordinates of the plurality of markers internal to the body and relative to a first beam isocenter of a first beam source of the first imaging modality; means for imaging the plurality of markers in a different second imaging modality; and means for determining second coordinates of the plurality of markers internal to the body and relative to a second beam isocenter of a second beam source of the second imaging modality, ... wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter

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at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging, as required by claim 49.

Arguments similar to those above for claim 1 apply to show that the combination of references are improperly combined to teach, do not teach, and are not enabled to teach the corresponding limits of claim 49 noted above (or benefits thereof).

Moreover, in addition to the reasons noted above, Appellants respectfully disagree with the rejection above for claim 49 for at least the reason that the cited references do not teach or enable that the apparatus further requires imaging internal markers where that the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine, wherein the first beam isocenter is a planned treatment beam isocenter, as required by claim 49. Mate teaches a primary purpose of allowing target 12 to be accurately positioned at a treatment machine isocenter by acceptably aligning target and machine isocenters 40 and 22 for radiation delivery from source 18 to irradiate a target (see paragraphs 35 and 39). Excited markers 30 and reference device 42 are located (not imaged) relative to the reference coordinate system 72 using array 34 of sensors 36 to detect the radio-frequency signals of markers 30 and reference device 42 (see Mate paragraphs 37, 48-55). The location of markers 30 as compared to the location of target 12 is calculated using reference device 42 which is at a known position relative to machine isocenter 22 (and thus is at a known position relative the target 12), and provides a radiofrequency signals detected and located the markers 30 by array 34 sensors 36 (see Mate paragraph 38). The location of markers 30 relative to the reference coordinate system 72, can be added by computer controller 38 to imaging data (see Mate paragraph 54-55). There is no description of markers 30 being imageable or being imaged. Instead Mate described that the RF location data "defines locations of each marker 30." (see Mate paragraphs 37-38, 60 and 62). However, Mate fails to show imaging internal markers using more than one x-ray imaging modality, where the second beam isocenter is a high energy beam of radiation of a treatment machine and the first beam isocenter is a planned treatment beam isocenter, as required by claim 49. Instead, Mate teaches that markers can be located by exciting markers 30 with excitation source 32 so that markers 30 resonate at a selected unique frequency and generate an underlying

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low energy radio-frequency magnetic signal measurable from outside body 14 by array 34 of sensors 36 (see paragraph [0036]).

The primary purpose and principle of operation of <u>Cosman</u> is to <u>coordinate external</u> markers for external treatment apparatus to specific targets within the body (see paragraphs 8 and 9). The camera of <u>Cosman</u> images the external markers relative to photons reflected from the external markers (see paragraphs 31 and 102). For example, Cosman teaches percutaneously fixing a stud section to the iliac crest bone of the pelvis during treatment, so that an array of external marker spheres can be attached to the stud above the surface of the skin at the time of treatment (see paragraph [0061] and Figure 3C). The markers are geometric objects to indicate positions of locations that are <u>visible to a camera</u> (see paragraph [0063]). Cosman requires camera imaged external fiducial markers 20, 21, 23 and 24 (see paragraph 64 and Figs. 1-3), although additional x-ray imaging is mentioned (see paragraphs 31 and 67). Cosman only describes that diagnostic X-rays from machines, or high energy X-rays for portal imaging can be used to visualize markers prior to treatment (paragraph 67). Moreover, the "index markers" mentioned at the end of paragraph 67 of Cosman refer to Cosman's external markers that are either secured to the patient's skin (see paragraphs 57-60) or attached to bone but exposed to the camera (e.g., they are internal studs that have external markers extended so that they are "visible" to camera; see paragraph [0061] and Figure 3C). However, Cosman does not teach or enable imaging internal markers using more than one x-ray imaging modality, where the second beam isocenter is a high energy beam of radiation of a treatment machine and the first beam isocenter is a planned treatment beam isocenter, as required by claim 49. Instead, Cosman only provides coordinating the location of externally visible fiducial markers that can be scanned by a camera (see paragraphs 24, 29-34, 39-41, 52, 61 and 68). For example, the primary purpose of Cosman is to have the markers external to the skin so that they can be imaged with a camera in order to provide an optical tracking system to compare the location of the markers in images picked up a camera system to align the target with the isocenter of a beam (see paragraphs [0064]-[0066] and Figure 3C).

Jaffray is cited for treatment imaging, but does not and can not be properly combined to teach or enable the above limits of claim 49 (or benefits thereof).

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3. <u>Independent claim 54</u>

Appellants respectfully disagree with the rejection above for claim 54 for at least the reason that the cited references do not teach or enable a system, comprising: a first beam source to generate an imaging beam having a first beam isocenter; a second beam source to generate a treatment beam having a second beam isocenter; a first imager coupled to receive the imaging beam, the first imager to image a plurality of markers, wherein at least a plurality of the markers are implanted completely internally in a body, in a first imaging modality; a second imager coupled to receive the treatment beam, the second imager to image the plurality of markers in a different second imaging modality; and a computer coupled to the first and second imagers, the computer to determine first coordinates of the plurality of markers relative to the first beam isocenter and internal to the body and determine second coordinates of the plurality of markers relative to the second beam isocenter and internal to the body, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging, as required by claim 54.

Arguments similar to those above for claim 49 apply to show that the combination of references are improperly combined to teach, do not teach, and are not enabled to teach the corresponding limits of claim 54 noted above (or benefits thereof).

4. <u>Dependent claim 62</u>

The dependent claims must be considered in their entirety. For instance, in addition to being dependent upon allowable base claims, Appellants disagree with the rejection above of claim 62 for at least the reason that the references do not teach the above noted limitations of imaging in a first and second modality of claim 1, as well as adjusting a position of a target volume within the body relative to a treatment beam using the plurality of internal markers imaged using the first imaging modality having an external source and the second imaging modality having an external source, as required by claim 62. Mate only teaches positioning a

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target for treatment radiation delivery (see paragraph 35 and 39) using implanted excitable markers located with RF sensors (see Figs. 1-7). Cosman only teaches that diagnostic X-rays or high energy X-rays can be used to visualize markers prior to treatment (see paragraph 67). Also, the "index markers" mentioned at the end of paragraph 67 of Cosman refer to Cosman's external markers that are either secured to the patient's skin (see paragraphs 57-60) or attached to bone but exposed to the camera (e.g., they are internal studs that have external markers extended so that they are "visible" to camera; see paragraph [0061] and Figure 3C). Jaffray is cited for treatment imaging, but does not and can not be properly combined to teach or enable the above limits of claim 62 (or benefits thereof). Thus, references do not contemplate the limits required by claim 62.

5. <u>Dependent claim 82</u>

In addition to being dependent upon allowable base claims, Appellants disagree with the rejection above of claim 82 for at least the reason that the references do not teach the above noted limitations of imaging in a first and second modality of claim 1, as well as wherein the first beam isocenter is determined at a treatment planning machine during a treatment planning stage. the second beam isocenter is a treatment machine beam isocenter during a treatment, and the treatment planning machine and the treatment machine are different machines, as required by claim 82. Mate only teaches positioning a target for treatment radiation delivery (see paragraph 35 and 39) using implanted excitable markers located with RF sensors (see Figs. 1-7). Cosman only teaches that diagnostic X-rays or high energy X-rays can be used to visualize markers prior to treatment (see paragraph 67). Also, the "index markers" mentioned at the end of paragraph 67 of Cosman refer to Cosman's external markers that are either secured to the patient's skin (see paragraphs 57-60) or attached to bone but exposed to the camera (e.g., they are internal studs that have external markers extended so that they are "visible" to camera; see paragraph [0061] and Figure 3C). Jaffray is cited for treatment imaging, but does not and can not be properly combined to teach or enable the above limits of claim 82 (or benefits thereof). Thus, references do not contemplate the limits required by claim 82.

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6. Dependent claim 88

In addition to being dependent upon allowable base claims, Appellants disagree with the rejection above of claim 88 for at least the reason that the references do not teach the above noted limitations of imaging in a first and second modality of claim 1, as well as wherein the first beam isocenter is a planned isocenter determined at a planning machine at a time of planning using an image from the first imaging modality, wherein the second beam isocenter is a treatment machine beam isocenter of a treatment machine at a time of treatment, and wherein the second imaging modality is arranged to provide an image of the patient at the treatment machine, as required by claim 88. Mate only teaches positioning a target for treatment radiation delivery (see paragraph 35 and 39) using implanted excitable markers located with RF sensors (see Figs. 1-7). Cosman only teaches that diagnostic X-rays or high energy X-rays can be used to visualize markers prior to treatment (see paragraph 67). Also, the "index markers" mentioned at the end of paragraph 67 of Cosman refer to Cosman's external markers that are either secured to the patient's skin (see paragraphs 57-60) or attached to bone but exposed to the camera (e.g., they are internal studs that have external markers extended so that they are "visible" to camera; see paragraph [0061] and Figure 3C). Jaffray is cited for treatment imaging, but does not and can not be properly combined to teach or enable the above limits of claim 88 (or benefits thereof). Thus, references do not contemplate the limits required by claim 88.

Hence, for at least all of the reasons above, Appellants respectfully request the Board overturn all of the rejections argued above.

C. The Patent Office rejects dependent claims 63-64 under 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0193685 to Mate et al. (Mate) in view of U.S. Publication No. 2002/0065461 to Cosman (Cosman) and U.S. Patent Pub. No. 2003/0007601 to Jaffray et al. (Jaffray) and further in view of U.S. Patent No. 6,073,044 to Fitzpatrick et al. (Fitzpatrick).

1. Dependent claim 63

The claims argued below do not stand or fall together but rather are argued separately in separate groups as indicated in this brief.

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The dependent claims must be considered in their entirety. For instance, in addition to being dependent upon allowable base claims, Appellants disagree with the rejection above of claim 63 for at least the reason that the references do not teach the above noted limitations of imaging in a first and second modality of claim 1, as well as estimating an adjustment to at least one of the body and a treatment beam in a treatment session, based on a determination of any change of spacing between imaged markers implanted in a target, over a course of multiple treatment sessions, and based on a number of visible markers in the imaged markers, as required by claim 63. Mate only teaches positioning a target for treatment radiation delivery (see paragraph 35 and 39) using implanted excitable markers located with RF sensors (see Figs. 1-7). Cosman only teaches that diagnostic X-rays or high energy X-rays can be used to visualize markers prior to treatment (see paragraph 67). Also, the "index markers" mentioned at the end of paragraph 67 of Cosman refer to Cosman's external markers that are either secured to the patient's skin (see paragraphs 57-60) or attached to bone but exposed to the camera (e.g., they are internal studs that have external markers extended so that they are "visible" to camera; see paragraph [0061] and Figure 3C). Jaffray is cited for treatment imaging, but does not and can not be properly combined to teach or enable the above limits of claim 63 (or benefits thereof). Fitzpatrick teaches registering two arbitrarily oriented three dimensional images is to align the coordinate systems of the two images (col. 1, lines 42-58). However, Fitzpatrick only teaches that the accurate selection and comparison of views of identical areas in images that have been obtained by imagers at different times or by images obtained essentially at the same time. Fitzpatrick does not provide any description of what is meant by "different times;" or whether different imagers or machines are used at different times. Thus, references do not contemplate the limits required by claim 63.

2. Dependent claim 64

In addition to being dependent upon allowable base claims, Appellants disagree with the rejection above of claim 64 for at least the reason that the references do not teach the above noted limitations of imaging in a first and second modality of claims 1 and 63, as well as estimating a number of positioning images needed for the treatment session based on a determination of any change of spacing between imaged markers implanted in a target, over a course of treatment, and based on the number of visible markers in the image, as required by claim 64. Mate only teaches positioning a target for treatment radiation delivery (see paragraph

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35 and 39) using implanted excitable markers located with RF sensors (see Figs. 1-7). Cosman only teaches that diagnostic X-rays or high energy X-rays can be used to visualize markers prior to treatment (see paragraph 67). Also, the "index markers" mentioned at the end of paragraph 67 of Cosman refer to Cosman's external markers that are either secured to the patient's skin (see paragraphs 57-60) or attached to bone but exposed to the camera (e.g., they are internal studs that have external markers extended so that they are "visible" to camera; see paragraph [0061] and Figure 3C). Jaffray is cited for treatment imaging, but does not and can not be properly combined to teach or enable the above limits of claim 63 (or benefits thereof). Fitzpatrick teaches registering two arbitrarily oriented three dimensional images is to align the coordinate systems of the two images (col. 1, lines 42-58). However, Fitzpatrick only teaches that the accurate selection and comparison of views of identical areas in images that have been obtained by imagers at different times or by images obtained essentially at the same time. Fitzpatrick does not provide any description of what is meant by "different times;" or whether different imagers or machines are used at different times. Thus, references do not contemplate the limits required by claim 64.

Hence, for at least all of the reasons above, Appellants respectfully request the Board overturn all of the rejections argued above.

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CONCLUSION

Accordingly, Appellants respectfully request that the Board overturn the rejection of Claims 1, 3, 5-16, 49, 51-58, 62-79, and 81-89.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN

Dated: 2011-07-23

By:

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1279 Oakmead Parkway Sunnyvale, California 94085-4040 Telephone (310) 207-3800 Facsimile (408) 720-8383 I hereby certify that this paper is being transmitted online via EFS Web to the Patent and Trademark Office, Commissioner for Patents, Post Office Box 1450, Alexandria, VA 22313-1450, on the date below.

Jessica Huester

Date

VIII. CLAIMS APPENDIX

The claims involved in this Appeal are as follows:

1. (Previously Presented) A method, comprising:

imaging a plurality of markers in a first imaging modality, wherein at least a plurality of the markers are implanted completely internally in a body;

determining first coordinates of the plurality of markers relative to a first beam isocenter and internal to the body;

imaging the plurality of markers in a different second imaging modality; and determining second coordinates of the plurality of markers relative to a second beam isocenter and internal to the body, wherein at least a plurality of said markers are implanted in soft tissue of the body, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging.

- 2. (Cancelled)
- 3. (Previously Presented) The method of claim 1, further comprising: correlating the second coordinates with the first coordinates; and calculating an offset between the first coordinates and the second coordinates for at least one of the plurality of markers.
- 4. (Cancelled)
- 5. (Original) The method of claim 3, further comprising adjusting a position of the plurality of markers based on the calculated offset.
- 6. (Original) The method of claim 1, further comprising identifying one or more of the plurality of markers that are imaged in the second imaging modality.

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- 7. (Original) The method of claim 6, wherein imaging the plurality of markers in the first imaging modality generates a first image and imaging the plurality of markers in the second imaging modality generates a second image.
- 8. (Previously Presented) The method of claim 7, wherein identifying one or more of the plurality of markers that are imaged in the second imaging modality comprises performing a 2D size and shape consistency test of a region of interest of the second image.
- 9. (Original) The method of claim 8, wherein the 2D size and shape consistency test comprises median filtering and connected component analysis.
- 10. (Previously Presented) The method of claim 8, wherein identifying one or more of the plurality of markers that are imaged in the second imaging modality comprises performing a 3D geometric consistency test of the region of interest of the second image.
- 11. (Previously Presented) The method of claim 10, wherein the 3D geometric consistency test comprises an epipolar coincidence constraint.
- 12. (Previously Presented) The method of claim 6, wherein identifying one or more of the plurality of markers includes identifying one or more non marker objects as one or more of the plurality of markers and wherein the method further comprises removing the one or more non marker objects from the image.
- 13. (Original) The method of claim 6, further comprising determining a position of one or more of the plurality of markers that are not imaged in the second imaging modality.
- 14. (Original) The method of claim 13, wherein the position is determined based on the relationship between the first coordinates and the second coordinates of the one or more of the plurality of markers that are imaged.
- 15. (Original) The method of claim 14, determining the position comprises: estimating a rigid body transform; and

applying the rigid body transform to the first coordinates to estimate the position of the one or more of the plurality of markers not imaged in the second imaging modality.

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16. (Original) The method of claim 13, wherein the position is determined manually by a user.

17-48. (Cancelled)

49. (Previously Presented) An apparatus, comprising:

means for imaging a plurality of markers in a first imaging modality, wherein at least a plurality of the markers are implanted completely internally in a body;

means for determining first coordinates of the plurality of markers internal to the body and relative to a first beam isocenter of a first beam source of the first imaging modality;

means for imaging the plurality of markers in a different second imaging modality; and means for determining second coordinates of the plurality of markers internal to the body and relative to a second beam isocenter of a second beam source of the second imaging modality, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging.

- 50. (Cancelled)
- 51. (Previously Presented) The apparatus of claim 49, further comprising:
 means for correlating the second coordinates with the first coordinates; and
 means for calculating an offset between the first coordinates and the second coordinates
 for at least one of the plurality of markers.
- 52. (Previously Presented) The apparatus of claim 51, further comprising means for adjusting a position of the plurality of markers based on the calculated offset.
- 53. (Previously Presented) The apparatus of claim 49, further comprising means for identifying one or more of the plurality of markers that are imaged in the second imaging modality.

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- 54. (Previously Presented) A system, comprising:
 - a first beam source to generate an imaging beam having a first beam isocenter;
 - a second beam source to generate a treatment beam having a second beam isocenter;
- a first imager coupled to receive the imaging beam, the first imager to image a plurality of markers, wherein at least a plurality of the markers are implanted completely internally in a body, in a first imaging modality;

a second imager coupled to receive the treatment beam, the second imager to image the plurality of markers in a different second imaging modality; and

a computer coupled to the first and second imagers, the computer to determine first coordinates of the plurality of markers relative to the first beam isocenter and internal to the body and determine second coordinates of the plurality of markers relative to the second beam isocenter and internal to the body, wherein the first imaging modality is an x-ray imaging modality, the first beam isocenter is an isocenter of an x-ray image system, the second imaging modality is an x-ray imaging modality, and the second beam isocenter is a high energy beam of radiation of a treatment machine, wherein the first beam isocenter is a planned treatment beam isocenter and the second beam isocenter is a treatment machine beam isocenter at a time of treatment, and wherein the first imaging modality is CT and the second imaging modality is one of kilo volt (kV) and mega volt (MV) imaging.

- 55. (Previously Presented) The system of claim 54, wherein the first imager is the second imager.
- 56. (Previously Presented) The method of claim 1, wherein implanting comprises injecting the markers into soft tissue of the body using a needle.
- 57. (Previously Presented) The method of claim 1, wherein implanting comprises expelling the markers into soft body tissue.
- 58. (Previously Presented) The method of claim 1, wherein imaging the plurality of markers in the first imaging modality occurs during a first treatment session, and imaging the plurality of markers in the second imaging modality occurs during a different second treatment session.

59-61. (Cancelled)

62. (Previously Presented) The method of claim 1 further comprising:

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adjusting a position of a target volume within the body relative to a treatment beam using the plurality of internal markers imaged using the first imaging modality having an external source and the second imaging modality having an external source.

63. (Previously Presented) The method of claim 1 further comprising:

estimating an adjustment to at least one of the body and a treatment beam in a treatment session, based on a determination of any change of spacing between imaged markers implanted in a target, over a course of multiple treatment sessions, and based on a number of visible markers in the imaged markers.

- 64. (Previously Presented) The method of claim 63, further comprising estimating a number of positioning images needed for the treatment session based on a determination of any change of spacing between imaged markers implanted in a target, over a course of treatment, and based on the number of visible markers in the image.
- 65. (Previously Presented) The method of claim 63, wherein the target is rigid and the number of visible markers is at least one.
- 66. (Previously Presented) The method of claim 65, wherein the adjustment is a patient position adjustment.
- 67. (Previously Presented) The method of claim 65, wherein the adjustment is a Multi-Leaf Collimator (MLC) position adjustment.
- 68. (Previously Presented) The method of claim 63, wherein the target is rigid and the number of visible markers is at least two.
- 69. (Previously Presented) The method of claim 68, wherein the adjustment is a patient orientation adjustment.
- 70. (Previously Presented) The method of claim 68, wherein the adjustment is a Multi-Leaf Collimator (MLC) rotation adjustment.
- 71. (Previously Presented) The method of claim 63, wherein the target is deformable and the number of visible markers is three or more.

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- 72. (Previously Presented) The method of claim 71, wherein the adjustment is a Multi-Leaf Collimator (MLC) shape.
- 73. (Previously Presented) The method of claim 64, wherein the target is rigid and the number of visible markers is three or more, and wherein the number of positioning images is two or more from different view angles suitable for triangulation.
- 74. (Previously Presented) The method of claim 64, wherein the target is deformable and the number of visible markers is three or more, and wherein the number of positioning images is at least one from a same view angle as a treatment beam angle.
- 75. (Previously Presented) The method of claim 64, wherein the target is deformable and the number of visible markers is three or more, and wherein the number of positioning images is two or more from different view angles suitable for triangulation.
- 76. (Previously Presented) The method of claim 1, further comprising emitting signals from the imaging sources of the first and second imaging modalities.
- 77. (Previously Presented) The method of claim 1, wherein the imaging sources of the first and second imaging modalities are located on two or more gantries.
- 78. (Previously Presented) The method of claim 9, wherein filtering comprises taking median intensity values of perimeter pixels around a center pixel being evaluated and subtracting the median intensity values from the center pixel to generate a filtered output pixel intensity value.
- 79. (Previously Presented) The method of claim 78, wherein the perimeter pixels are pixels on a perimeter of an approximate circle around the center pixel.
- 80. (Cancelled)
- 81. (Previously Presented) The method of claim 79, wherein the radius of the approximate circle is greater than a width of the marker.
- 82. (Previously Presented) The method of claim 1, wherein the first beam isocenter is determined at a treatment planning machine during a treatment planning stage, the second beam

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isocenter is a treatment machine beam isocenter during a treatment, and the treatment planning machine and the treatment machine are different machines.

- 83. (Previously Presented) The method of claim 1, wherein the first imaging modality is one of a CT imaging, a kilo volt imaging, and a mega volt imaging.
- 84. (Previously Presented) The method of claim 1, wherein one imaging source of the first imaging modality is located on a gantry of a treatment planning machine, and an imaging source of the second imaging modality is located on a different treatment machine.
- 85. (Previously Presented) The method of claim 1, further comprising measuring radiation received by at least one of the implanted completely internally plurality of markers during a treatment session.
- 86. (Previously Presented) The method of claim 58 further comprising measuring radiation received by at least one of the implanted completely internally markers during the first treatment session and during the second treatment session.
- 87. (Previously Presented) The method of claim 1 further comprising: implanting the plurality of implanted completely internally markers into soft tissue by expelling the markers into the soft tissue of the body using a needle; treating the body with high energy radiation of the high energy treatment beam.
- 88. (Previously Presented) The method of claim 1, wherein the first beam isocenter is a planned isocenter determined at a planning machine at a time of planning using an image from the first imaging modality, wherein the second beam isocenter is a treatment machine beam isocenter of a treatment machine at a time of treatment, and wherein the second imaging modality is arranged to provide an image of the patient at the treatment machine.
- 89. (Previously Presented) The method of claim 88, wherein the first imaging modality is a 3D CT image including the markers, and the second imaging modality is a 2D MV x-ray treatment beam image including the markers.

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IX. EVIDENCE APPENDIX

Not Applicable.

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X. RELATED PROCEEDINGS APPENDIX

There are no other appeals or interferences that will directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

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